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Continuation sheets of this form	0
Description	7
Claim(s)	7
Abstract	—
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Priority documents	—
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Statement of inventorship and right to grant of a patent (Patents Form 7/77)	2 PAGES
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12. Name, daytime telephone number and e-mail address, if any, of person to contact in the United Kingdom

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Moulding Process

Field of the invention

The present invention relates to a method and apparatus for producing a plurality of ophthalmic lenses and to ophthalmic lenses thus produced.

~~Background art~~

The conventional method of producing ophthalmic lenses is to form a lens blank by polymerisation of liquid monomers in a mould and to subsequently mechanically lathe the lens blank into a finished lens and to polish the lens to remove imperfections. This method is labour-intensive and expensive.

In recent times, double-sided cast moulding (DSCM) processes have been developed. These processes generally involve the initial production (by moulding) of single-use male and female moulds. Liquid monomers are then deposited into the female mould and the male and female moulds are mated together. The monomers are then cured by heating to form the desired polymer lens (the term 'cured' means that the material being cured is rendered insoluble in a solvent in which it was previously soluble and the term is thus a generic term covering more specific terms such as polymerisation, crosslinking, vulcanisation etc.). The lens is removed from the mould and is washed to extract unreacted monomers and/or solvents. The moulds are then disposed and the lenses are packed in final packs.

It is to be noted that the controllable moulding process in such a DSCM process is the moulding of the single-use moulds rather than that of the lenses themselves. The most common way of producing the single-use moulds is to produce them between two platens with removably mounted, precisely machined inserts mounted on the platens. A change of mould shape (in order to

produce a lens with different optical qualities) is achieved through a change of inserts in the moulding platen. The inserts are generally created on a precision lathe and are polished to remove surface imperfections. Some particular lens optical qualities are created by controlling the orientation of the male to the female mould.

Thus in a DSCM process, it is the shapes of the disposable moulds which determine the shape and power of the final lens.

US 5,508,317 discloses an improvement to standard DSCM in which an aqueous solution of prepolymer is introduced into the mould and curing is effected by photo-crosslinking. It is claimed that this gives the advantage of allowing the washing/extraction step of standard DSCM to be dispensed with.

Other improvements which have been proposed to DSCM include making one of the moulds reusable and making at least one of the mould UV-transparent to allow UV curing.

WO 98/42497 discloses the curing of lenses produced using a DSCM process by the use of UV alone.

US 4,673,539 and US 4,786,446 disclose a different production process approach involving creating a shaped thermoplastic hydrogel precursor by the thermoforming of a particular form of uncrosslinked polymer (one containing the product of an ethylenically-unsaturated monomer bearing at least one trihaloacetoxy-substitute group), subsequently solvolyzing the precursor in the presence of a diluent in order to form a polymeric shaped article and finally hydrating the shaped article to provide an ophthalmic lens. This process is claimed to produce lenses with high and controllable water sorbency characteristics.

DSCM processes suffer from problems with quality variation in production caused both by control of mould quality in the two-step casting procedure and by variability in the curing process.

In the practical environment of a commercial production process, the curing process is always subject to variations in monomer mixtures and variations in monomer mixture components. A practical curing process is also subject to changes in cure rates due to fluctuations in energy of the (normally thermal) curing source.

All prior art processes suffer from problems of manufacturing efficiency - being, at best, batch processes requiring significant human involvement and, at worst, effectively custom-manufacturing processes requiring skilled operators for each and every process step. Due to this, the cost of production of ophthalmic lenses is relatively high.

It is an object of this invention to provide a method for producing ophthalmic lenses with improved manufacturing efficiency compared to prior art methods. In particular, the method of the current invention provides increased consistency and quality of production as well as a reduction in the quantity of process steps required when compared with priot art methods.

It is a further object of this invention to reduce the quantity of material consumed by the moulding and curing process for an ophthalmic lens and thus, in this way, to reduce the environmental impact of the moulding and curing process.

It is a further object of this invention to also reduce the environmental impact of the moulding and curing process by reducing the amount of wet-chemistry and associated chemical waste products when compared with prior art processes.

Summary of the Invention

The present invention overcomes the problems mentioned above through provision of a method of producing a plurality of ophthalmic lenses according to claim 1.

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Further desirable features and desirable embodiments as well as an apparatus for executing the method of the invention and ophthalmic lenses produced using the method and/or apparatus are detailed in claims 2 to 39.

The current invention has many advantages over prior art production methods for ophthalmic lenses:

When using the current invention, there is no loss of precision in lens shape due to allowances that must be made in prior art methods both for shrinkage in the moulds as they cool and for shrinkage in initial monomer volume due to polymerisation (which is typically about a 16% shrinkage which is very difficult to control accurately).

When using the current invention, there is no need to store and maintain an inventory of single-use moulds, which are not currently in use.

Since there is no need for producing disposable moulds, which are not part of the final product, the current invention produces a dramatic reduction in waste material.

Due to using more easily-controllable process steps, lenses produced using the current invention have an improved accuracy of lens power, improved surface quality and improved power consistency vis-à-vis those produced using prior art methods.

Some particular embodiments of the current invention provide improved sterilisation, packaging and in-line inspection steps over prior art methods of production. These improvements can also lead to a reduced manufacturing area requirement.

Compared to known methods of using reusable glass moulds, the current invention has the advantage that mould washing and inspections for mould cleanliness is not required as frequently.

In the known methods that use curing by UV alone, UV-absorbing agents cannot be incorporated into lenses, since these then inhibit the polymerisation process. In the current invention this is not a limitation.

Other aspects and advantages of the invention will be clear from a study of the following detailed description and drawing in which a particular embodiment of the invention is described consisting of a manufacturing process for contact lenses, wherein a contact lens is used as a particular example of an ~~ophthalmic lens and e-beam irradiation is used as a particular~~ example of a means of application of high energy.

Brief Description of Drawings

Figure 1: A schematic flow diagram of the process steps of a particular embodiment of the invention

Detailed description

Figure 1 shows a schematic representation of an embodiment of the invention. A roll of uncrosslinked or partially crosslinked polymer in the form of sheet, 1, is provided and is transported to a thermoforming area, 14. Prior to entering the thermoforming area the polymer sheet is inspected by means of an automatic vision system, 2, for significant defects, such as tears, that would result in an unsatisfactory final product. At the same time the polymer sheet is heated to temperature where it is easy to shape the polymer into the desired shape as defined by the inserts in the thermoforming process and yet the polymer sheet still retains sufficient strength for it to be manipulated through the process. The polymer sheet is then passed through the thermoforming area where platens, 3 and 9, containing the optical quality inserts, shape the polymer sheet into the desired form. Depending on the properties of the polymer sheet

the inserts and the platens may be cooled or heated as required to obtain the required flow and optical clarity in the shaped part. The use of pressure or vacuum through the platens or inserts may also be used to achieve the desired shape. The optical inserts and their bodies, which fit into the platen, are so designed that the formed shape is not fully detached from the original polymer sheet and that after the forming process has been completed the formed shapes are moved forward with the polymer sheet, 12.

The formed parts are then inspected by means of an automated vision system, 4, for defects. The polymer sheet with formed shapes may then be stored for use in the future or processed immediately as a continuous or semi-continuous process by passing it through an electron beam, 5. The exposure of the polymer sheet and the formed parts to the electron beam is so controlled that the polymer becomes substantially sterile. The formed parts are separated from the polymer sheet and deposited in a final package within a sterile environment. This final package has been treated so that it is effectively sterile and is maintained within an environment that keeps it, and the formed shape, sterile. The pack and formed shape are transported within this environment to a dosing station, 7, where aseptic or sterile packaging/hydration solution is added. The pack, solution and shaped part are then sealed at station, 8, also within the sterile area, with a sterile foil before leaving the process area for final labelling. To those skilled in the art the process steps may be changed. For example the lenses may be inspected after they have been separated from the polymer sheet. It may also be that the sterilisation could occur, either alone or in addition to previous treatment, in the final package, and that this treatment could be the use of high energy irradiation on other methods such as ethylene oxide that do not affect the performance of the lens.

One embodiment of the invention is the process by which the ophthalmic lens is directly formed from a polymer by moulding. The various embodiments of the invention are described with respect to the preferred ophthalmic lens embodiment; however,

various embodiments of the invention are not limited to a specific type of moulding. "Ophthalmic lenses", used herein, refers to any medical or vision correction devices that are used in the ocular environment, including contact lenses, intraocular lenses, corneal onlays and inlays, ocular drug delivery devices, ocular wound healing devices and the like.

"Polymer", as used herein, refers to the material from which the initial lens shape is produced and includes copolymers, mixtures of polymers, interpenetrating network systems, polymer systems ~~that are already partially crosslinked, polymer to which~~ additives have been added to reduce UV transmission, for therapeutic purposes, to add colour for cosmetic reasons and the like.

The energy source and radiation used for sterilisation may vary, together with time of exposure, depending on the polymer composition and the properties required.

In one preferred example of an ophthalmic lens, that of a hydrated contact lens, the final lens may comprise water content from 20 to 75%, by weight, preferably from 35 to 55% and more preferably from 35 to 45%.

In another example exposure to radiation may be to crosslink the lens. In yet another example it is possible that the required levels of sterility and crosslinking can be achieved simultaneously.

Other embodiments include products other than ophthalmic lenses, for example polymer products that may be thermoformed and require to be packed in sterile conditions. Such examples include artificial limbs and joints. A further embodiment includes polymer containers for foods, especially those that are dehydrated, e.g. dried milk and re-hydration materials, where purity and long life stability are requirements. A yet further embodiment includes the combination of more than one forming process to form 3-dimensional products.

CLAIMS

1. A method of producing a plurality of soft contact lenses, which comprises the following process steps:

A Providing a polymer, said polymer being water-soluble above a certain temperature and said polymer being provided in solid phase;

B Physically forming said polymer into a plurality of dry contact lens forms using any one of the group of physical forming processes from the group consisting of thermoforming or vacuum forming or pressing or hot moulding or cold moulding or compression moulding or injection moulding.

C Hydrating and thereby swelling said plurality of dry contact lens forms at a temperature below said certain temperature in an aqueous solution to form said plurality of soft contact lenses, whereby said plurality of soft contact lenses maintain a substantially stable lens shape.

2. A method of producing a plurality of soft contact lenses according to claim 1, wherein said polymer is provided in the form of a polymer sheet.

3. A method of producing a plurality of soft contact lenses according to claim 2, wherein said plurality of dry contact lens forms are removed from the polymer sheet at a stage after step B by the use of a laser cutting device.

4. A method of producing a plurality of soft contact lenses according to any of claims 1 to 3, in which the said polymer is chosen from the group consisting polyvinyl alcohol or a copolymer of polyvinyl alcohol and polyvinyl acetate or polyethylene-maleic-anhydride or polymethyl-hydroxy-propyl-cellulose or copolymers of methyl acrylate or ethyl acrylate with ethylene or their hydroxy derivatives.

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5. A method of producing a plurality of soft contact lenses according to any preceding claim, in which said certain temperature is approximately 50°C, whereby said polymer is only soluble in water at a temperature exceeding approximately 50°C.

6. A method of producing a plurality of soft contact lenses according to any preceding claim, in which said certain temperature is approximately 65°C, ~~whereby said polymer is only soluble in water at a~~ temperature exceeding 65°C.

7. A method of producing a plurality of soft contact lenses according to any preceding claim, in which said polymer is a copolymer of polyvinyl alcohol and polyvinyl acetate where the degree of hydrolysis, as measured by saponification, is at least 96% mol based on the original polyvinyl alcohol.

8. A method of producing a plurality of soft contact lenses according to any preceding claim, in which said physical forming step B comprises the following sub-steps:

B.1 Heating said polymer to a temperature that

a) is near to the softening temperature of the polymer, whereby thermoforming of said polymer is possible, but

b) is below the melting point of said polymer, whereby the physical integrity of said polymer is maintained; and

B.2 Thermoforming said plurality of contact lenses through application of pressure to said polymer.

9. A method of producing a plurality of soft contact lenses according to claim 8, in which said thermoforming sub-step involves compression of the polymer between two forms or platens.

10. A method of producing a plurality of soft contact lenses according to any of claims 2 to 9, in which at least immediately subsequently to said physical forming step B, said plurality of dry contact lens forms remain at least partially attached to said polymer sheet.

11. A method of producing a plurality of soft contact lenses according to claim 10, in which said polymer ~~sheet is used as a transport medium or carrying~~ mechanism for said plurality of dry contact lens forms through multiple steps of the method of production.

12. A method of producing a plurality of soft contact lenses according to any of the preceding claims, in which the physical forming step B involves the use of moulds and said polymer is placed between said moulds which are pressed together to form said plurality of contact lenses.

13. A method of producing a plurality of soft contact lenses according to any of the preceding claims, in which an application of high energy is arranged to sterilise said plurality of dry contact lens forms and/or said plurality of soft contact lenses.

14. A method of producing a plurality of soft contact lenses according to claim 13, in which the application of high energy involves irradiation by a form of high energy chosen from the group consisting of electron beam irradiation or gamma irradiation or microwave irradiation or ultraviolet irradiation.

15. A method of producing a plurality of soft contact lenses according to any of the preceding claims, which comprises the further step of

D transferring the plurality of dry contact lens forms to a plurality of final packs.

16. A method of producing a plurality of soft contact lenses according to claim 15, in which, before the transferring step D, the final packs are sterilised.

17. A method of producing a plurality of soft contact lenses according to claim 15 or 16, in which, either before or after the transferring step D, aseptic or sterile solution is added to the sterile final packs, which solution acts to hydrate and swell the lenses as per step C.

18. A method of producing a plurality of soft contact lenses according to claim 17, in which the polymer material of the dry contact lens forms undergo a chemical reaction, such as hydrolysis, in the final pack in order to form the final material.

19. A method of producing a plurality of soft contact lenses according to any of claims 15 to 18, in which, either before or after the transferring step D, the dry contact lens forms are washed to remove soluble material.

20. A method of producing a plurality of soft contact lenses according to any of claims 15 to 18, in which the contact lenses are not washed to remove soluble material.

21. A method of producing a plurality of soft contact lenses according to any preceding claim, in which all process steps subsequent to step B are carried out without further human contact or handling.

22. A method of producing a plurality of soft contact lenses according to any preceding claim, which method

is automated or semi-automated to run in a continuous or semi-continuous manner.

23. A method of producing a plurality of soft contact lenses according to any of the preceding claims, which further involves quality control inspections on the dry contact lenses forms only.

24. A method of producing a plurality of soft contact lenses according to any of the preceding claims, ~~which involves either visual quality control~~ inspections or quality control inspections using an optical system.

25. A soft contact lens produced according to a method of producing a plurality of soft contact lenses according to any of the preceding claims.

26. An apparatus for carrying out a method of producing a plurality of soft contact lenses according to any of claims 1 to 24 comprising:
- first transporting means for transporting said polymer to a physical forming means;
- physical forming means for physically forming said polymer into said plurality of dry contact lens forms;
- second transporting means for transporting said plurality of dry contact lens forms from said physical forming means to a high energy application means.
- high energy application means for applying high energy to said contact lenses.

27. An apparatus according to claim 26 in dependence upon either claim 2 or any of claims 3 to 24 in dependence upon claim 2, wherein, said transporting means comprises driven and/or undriven roller means for transporting said polymer sheet.

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28. An apparatus according claim 27 in which said physical forming means comprises a plurality of forms or platens arranged so as to press together to form the polymer sheet into the dry contact lens forms.

29. An apparatus according to claim 28 in which at least one of said plurality of forms or platens is provided with heating means whereby said polymer sheet may be heated in order to facilitate physical forming of the polymer sheet into the dry contact lens forms.

30. An apparatus according to either of claims 28 or 29 in which said plurality of platens are removably connectable with a plurality of male and female inserts, which inserts are formed to appropriate shapes to form the dry contact lens forms to desired optical specifications.

31. An apparatus according to claim 30 in which the inserts are arranged such that pressure (either positive or negative) may be applied through them.

32. An apparatus according to any of claims 26 to 31 which further comprises packaging means for transferring said dry contact lens forms from said high energy application means into final packs.

33. An apparatus according to claim 32 in which said packaging means is arranged to carry out packaging in a substantially sterile environment.

34. An apparatus according to either of claims 32 or 33 in which said packaging means comprises removing means for removing said dry contact lens forms from the polymer sheet, when said sheet of material is used as a transport medium or carrying mechanism according to claim 11.

35. An apparatus according to claim 34 in which said removing means is a laser cutting means.

36. An apparatus according to claim 35 in which said laser cutting means comprises a CO_2 laser.

37. An apparatus according to any of claims 26 to 33 in which a laser cutting means is provided for cutting and thereby forming the circumferential edges of the dry contact lens forms.

38. An apparatus according to any of claims 26 to 37 in which said high energy application means comprises an electron beam irradiation means.

39. A soft contact lens produced by an apparatus according to any of claims 26 to 38.

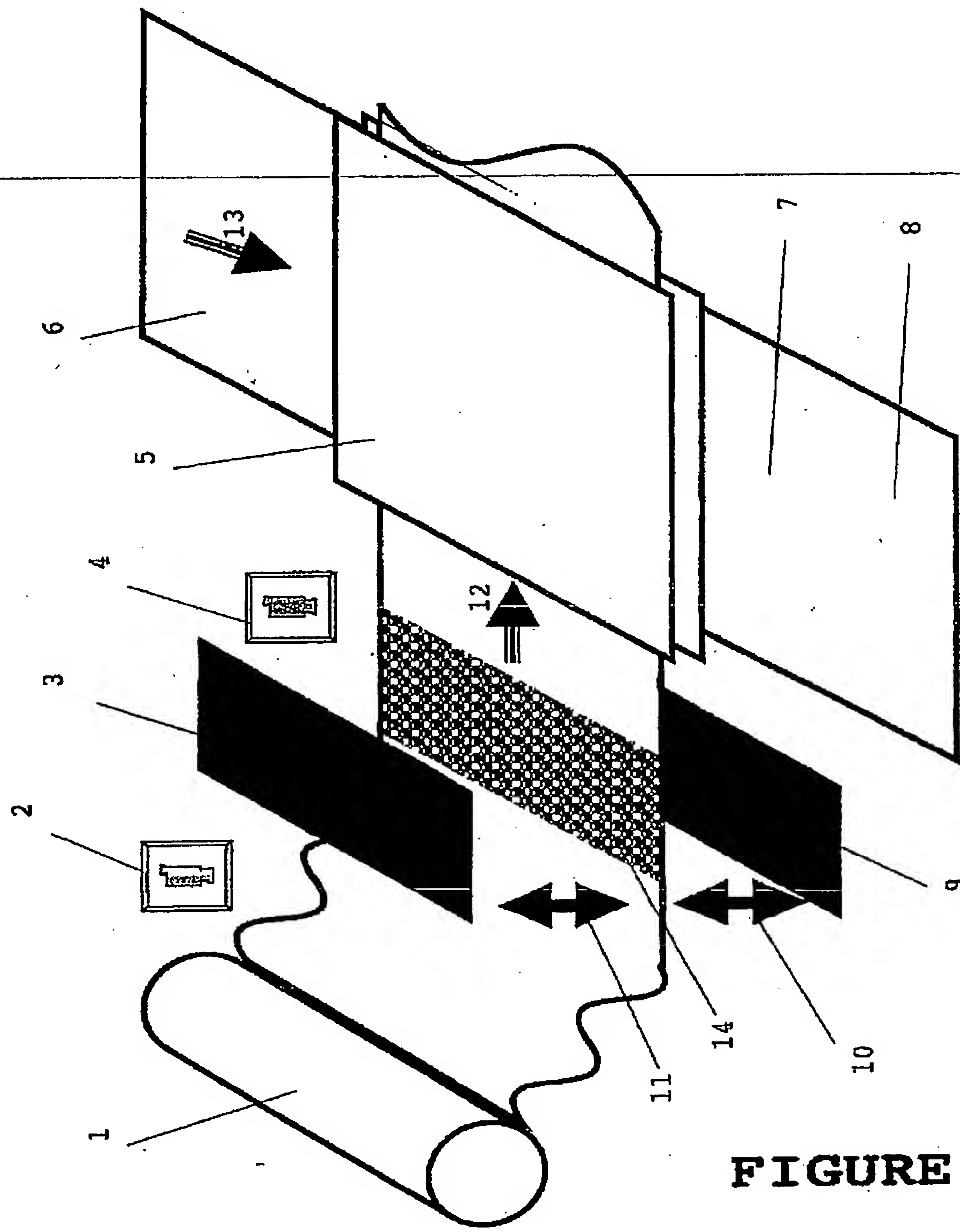

FIGURE 1